# **The Researchers & Scientists**

Through their contributions to research and science, these exemplary individuals make the R&D engine run.

#### From Researcher to CEO

**INTERNATIONALLY KNOWN FOR HIS WORK IN PAIN,** Daniel B. Carr, M.D., was the Saltonstall Professor of Pain Research in the departments of anesthesia and medicine at Tufts-New England Medical Center. He also has served as vice chairman for research of Tufts-New England Medical Center's department of anesthesia and continues to codirect the multidisciplinary Master of Science degree program in pain research, education, and policy at Tufts University School of Medicine.

He also has been a principal investigator on numerous clinical studies of pain and analgesia. A recognized expert in the field, Dr. Carr has received many awards and honors from leading professional organizations and healthcare institutions worldwide for his work.

Dr. Carr is credited with having a positive beside manner, which will come in handy as he approaches his new position as CEO and chief medical officer of Innovative Drug Delivery Systems Inc. (IDDS). Dr. Carr joined IDDS as chief medical officer in September 2004 and the responsibilities of CEO were added in July 2005. He joined IDDS full time after having been on the company's scientific advisory board for five years. He also served as an advisor to the FDA, as well as a consultant for numerous pharma companies that have pain franchises. Dr. Carr saw the IDDS portfolio of product candidates as meeting a crucial need for safe, proven analgesic products delivered in a simple, easy-to-use fashion.

Dr. Carr has authored or contributed to more than 100 articles, book chapters, and books on therapies for pain. A graduate of Columbia College and Columbia University, Dr. Carr trained in internal medicine at Columbia-Presbyterian Medical Center and later at Massachusetts General Hospital, where he continued his training in internal medicine, endocrinology, and anesthesiology. He is a diplomate of the American Boards of Internal Medicine and Anesthesiology and the American Board of Pain Medicine, and he holds the Certificate of Added Qualification in Pain Management from the American Board of Anesthesiology.

Daniel B. Carr, M.D., is one of the premier experts when it comes to pain and is bringing his extensive experience to Innovative Drug Delivery Systems Inc., a small biotech company, where he is playing double duty as CEO and Chief Medical Officer.



### **Dr. Boris Golubtsov**

Building Cultural Bridges

IN THE BOOMING WORLD OF INTERNATIONALLY OUTSOURCED CLINICAL TRIALS, BORIS GOLUBTSOV, M.D., PH.D., IS A CULTURAL ARCHITECT. By helping to bridge cultural gaps, he has an optimistic, can-do attitude toward conducting large clinical trials in Eastern Europe and has helped Eastern European investigators become real partners in the scientific community.



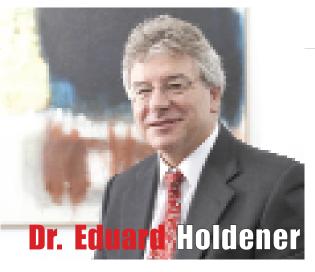
Though CROs, large and small, are gaining a real appreciation for the promise of Eastern Europe as a mecca for clinical research, there's nothing quite like true insight and first-hand knowledge of a region.

As head of operations in Central and Eastern Europe for Chiltern International Ltd., Dr. Golubtsov believes the best way to overcome barriers is maintaining regular contact, appreciating the constraints that both sides face, and finding ways to merge the Western approach with the Eastern European approach.

Born and raised in the Ukraine, Dr. Golubtsov understands the Eastern European experience, where years of Communism created a "nanny state." It's these types of cultural insights that give him a clear appreciation for how investigators will behave in difficult situations. He has encouraged Eastern European investigators to become more proactive through regular training sessions, while at the same time he has introduced the company's Western European staff to their Eastern European colleagues. He highlights the benefits of collaboration, reinforcing that although there are challenges to overcome, everyone benefits from successful partnerships.

Breaking down the psychological borders between East and West has been hugely gratifying to Boris Golubtsov, M.D., Ph.D., who remembers all too well the political and cultural isolation that Eastern Europeans were forced to live under for decades. As Head of Operations in Central and Eastern Europe for Chiltern International Ltd., he is building cultural and professional bridges.





# Working All the Angles

WITHOUT EVER SACRIFICING PATIENT SAFETY OR

**SKIRTING REGULATORY GUIDELINES**, Eduard E. Holdener, M.D., approaches drug development from a different point of view with the goal of getting new medicines to patients faster. Working within the constraints of a highly regulated industry, the global head of

straints of a highly regulated industry, the global head of pharmaceutical drug development and chief medical officer at Roche believes that there is room for out-of-the-box thinking as long as it is aligned with the company's strategy of delivering clinically differentiated medicines.

Leading by example and extolling the values of good communication, accessibility, reliability, consistency, fairness, empowerment, flexibility, and hard work, Dr. Holdener challenges his people — 3,000 employees worldwide — to think differently and to look at the drug-development process from many different angles. In so doing, he knows substantial gains can be achieved, such as faster trials, less costly projects, and enhanced safety and efficacy for patients. The ultimate goal is to create innovative medicines that are either first-in-class or best-in-class.

Within the classical phases of drug development, Dr. Holdener believes that applying a creative approach toward developing medicines can greatly shorten the overall time needed to bring a drug to market.

Dr. Holdener provides a real-world example of how thinking differently allowed Roche to take the lead in the global influenza market. Although the global development program for the flu drug at the time was well advanced in Phase III, its program in Japan was significantly behind that of its main competitor. To catch up, Roche won agreement from the Japanese health authority to implement an innovative development strategy centered on a comparative Phase I safety and PK-PD study with healthy Japanese and non-Japanese volunteers. The trial clearly demonstrated that the Roche drug acted the same in both populations. These data allowed the company to proceed directly to Phase III trials in Japan and to deliver the medicine to that market several years ahead of schedule, closing the time gap with its competitor. The medicine has established its place in the global market as a safe, effective, and convenient medicine in both the prevention and treatment of influenza.

Streamlining the drug-development process is the desire of all researchers. Eduard E. Holdener, M.D., Global Head of Pharmaceutical Drug Development and Chief Medical Officer at Roche, has found a way to achieve this goal by taking some nontraditional approaches.

# SUSAN ORR A Circuitous Path

THE ROAD FROM PRACTICING OPTOMETRIST TO CLINICAL PHARMACOLOGIST

**IS CERTAINLY LESS TRAVELED.** For Susan Orr, O.D., who currently is assistant director of clinical pharmacology at Alcon Inc., it was the right route to a fulfilling career. After graduating from the School of Optometry in Ontario, she established an optometric clinic, where she practiced for 10 years, and at the same time was involved in clinical trials as an investigator. Ms. Orr joined Alcon in 1997, after relocating to Dallas. Following positions in clinical glaucoma and international development, Ms. Orr moved to clinical pharmacology. She finds reward in motivating others and passing on her enthusiasm for science and the products that clinical pharmacology delivers.

Susan Orr, O.D., Assistant Director of Clinical Pharmacology at Alcon Inc., considers the most important component of her work to be her colleagues; the support, knowledge, and professionalism that team members bring to each project is inspiring.

# A Global Research Perspective

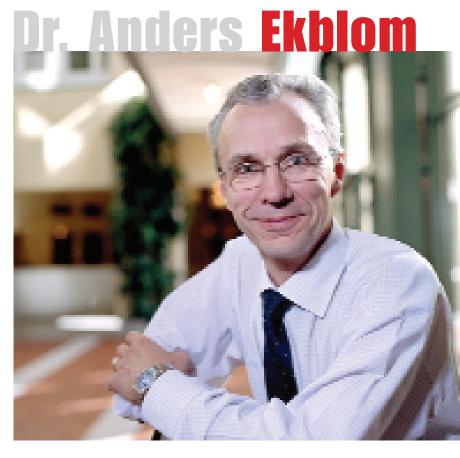
TACKLING HEAD-ON THE CHALLENGES OF MANAGING A CROSS-FUNCTIONAL TEAM ACROSS GEOGRAPHIC LOCATIONS IS NO EASY TASK, but keeping an open mind enables Anders Ekblom, M.D., Ph.D., D.D.S., to see new opportunities for drug development.

Going forward, Dr. Ekblom, VP of strategy, portfolio and alliances for global discovery, R&D, at AstraZeneca, believes that the industry needs to harness innovation more effectively and to develop the good opportunities faster and with a higher quality. As a result of the biological revolution that has taken place in the past few years, as well as the integration of basic and clinical science, he is excited by the clinical possibilities of having better validated molecular and disease targets to work on in a more predictive way. With regard to drug-development technologies, one approach that he will be following closely is measuring several processes simultaneously in cells and systems, instead of sequentially, to get a better understanding of what happens to optimize treatment approaches.

To enhance his company's global capabilities, Dr. Ekblom and his teams are embracing a different set of technologies — teleconferencing, videoconferencing, and Internet-based meetings — that allow for a high-degree of availability for spontaneous brainstorming and strategy sessions. He also has been experimenting with special software solutions that enable teams to be more effective online. This, combined with regular face-to-face contact, provides a basis for teams to perform well. Dr. Ekblom believes that by combining technology and traditional in-person meetings the team has the best chance to optimize global performance and delivery.

And his team appreciates Dr. Ekblom's pragmatic and empowering leadership style, as well as the time and effort he takes to make personal connections, provide coaching, and develop their careers.

Dr. Ekblom takes inspiration from working with, and learning



from, innovative people who are dedicated to what they do and are focused on delivery. He says he is fortunate to be working in an industry that aims to make life better for people through new opportunities.

With deep scientific insights and an acute understanding of business needs, Anders Ekblom, M.D., Ph.D., D.D.S., Associate Professor, VP of Strategy, Portfolio & Alliances, Global Discovery, R&D, at AstraZeneca is successfully leading a global cross-functional team.

#### A Remarkable Scientist

A RESEARCH SCIENTIST EXTRAORDINAIRE, A MAN WHOSE VAST CONTRIBUTIONS TO VACCINE DEVELOPMENT HAVE SAVED MILLIONS OF LIVES, A MAN WHO CHANGED THE WORLD. These are some of the accolades that rightly belong to the late Maurice R. Hilleman, Ph.D., one of Merck's most remarkable scientists.

Dr. Hilleman joined Merck in 1957 as director of the newly formed department of virus and cell biology research. He retired in 1984, though he continued to visit the Merck campus regularly. He also traveled extensively after retiring, acting as an advisor and statesman on infectious diseases. At the time of his death, on April 11, 2005, he was adjunct professor of pediatrics, School of Medicine, University of Pennsylvania, Philadelphia.

During his prolific career, Dr. Hilleman developed some of the most successful vaccines in history. Today, millions of children worldwide are immunized against diseases, such as mumps, measles, chicken pox, and rubella that caused severe disabilities and even claimed lives, thanks to the brilliance of Dr. Hilleman. He also pioneered vaccines for varicella, hepatitis A, hepatitis B, adenoviruses, and the evolution of

vaccines against meningitis and pneumonia. Humans are not the only species to have benefited from his discoveries; in 1971 he developed a vaccine for a viral infection that causes lymphoma in chickens. For a man raised on a farm in Montana, such a development was fitting.

In addition to these contributions, Dr. Hilleman was also a codiscoverer of the adenoviruses, and he discovered changes in the flu virus known as "drift." Knowing what to look out for enables public-health agencies to track new flu viruses and create vaccines to prevent them.

"Dr. Maurice Hilleman created a legacy of accomplishment and achievement that dwarfs that of any other scientist working today," said Adel A. F. Mahmoud, M.D., Ph.D., president of Merck Vaccines. "His work has saved literally millions of lives and has protected many millions more from disease."

Over the years, Merck paid tribute to Dr. Hilleman's discoveries in the noblest way possible: by marketing them at a time when preventive medicine was not understood, as well as giving much away. The company continues Dr. Hilleman's legacy with ongoing research into vaccines.

"Vaccinology is still a field in which dreams can be turned into realities," the late Maurice R. Hilleman, Ph.D., once said. "There are plenty of uncertainties but if you stick to it, you can do what seems impossible."



# Allen Roses

# A Scientist with Influence

**IF YOU ASK HIM WHAT HIS JOB IS, HE WILL TELL YOU HE IS A SCIENTIST.** Although as senior VP of genetics research and a member of the Research and Development Executive Committee at Glaxo-SmithKline, Allen David Roses, M.D., also is an administrator, a manager, and an executive; his primary role has always been and will always be that of a scientist.

In 1997, Dr. Roses left the life and legacy he built over two decades as a clinical neurologist and professor at Duke University. He wanted to

improve the quality of medicine in a way that he believed he couldn't in an academic environment. In his eight years at GlaxoSmithKline he has used the resources of the company and the industry to forge inroads into the frontiers of pharmacogenetics.

His peers credit him with actively leading the industry to implement pharmacogenetics in clinical development. Dr. Roses believes his impact at GlaxoSmithKline has changed the way the company looks at science, genetics and genomics, and the practice of pharmacogenetics, as well as the way targets are evaluated.

When he joined the former Glaxo Wellcome Research and Development Executive Committee as VP and worldwide director of genetics in 1997, he was charged with organizing genetic strategies leading to susceptibility gene discovery, developing and implementing a pharmacogenetics strategy, and integrating genetics into medicine discovery and development.

Being involved at the earliest stages of pioneering a new field of science has presented some challenges. Mainly, convincing the leadership of the organization that what he was, and is, doing has validity and that there is a business value to make the company successful. Dr. Roses has met this challenge head on by focusing on experiments and studies that demonstrate the positive impacts of the technology.

With the support from two heads of R&D, as well as a management committee that respects his opinion because of his honesty and dedication to the science, Dr. Roses is able to achieve his one professional desire: being a scientist in a major corporation that is making a difference.

Allen David Roses, M.D., Senior VP of Genetics Research and a member of the Research and Development Executive Committee at GlaxoSmithKline, views himself as a scientist who just happens to be in a position of influence.

# Dr. Lorin Roskos

# A Leader in Biologics

#### MOTIVATED BY SCIENTIFIC DISCOVERY AND

**LOGIC,** Lorin Roskos, Ph.D., senior director of Abgenix Inc., has become a leader in the development of biologics. He has been able to transfer preclinical information obtained in animal models, *in vitro* and *in silico*, to applicable information with high predictive value in human clinical studies. Through his research, Dr. Roskos has been able to not only minimize the cost but the associated time of the drug-development process. Additionally, he has presented papers on modeling and simulation as a way to facilitate the understanding of translational research, and he has written several scientific papers on his preclinical and other work.

Dr. Roskos is considered to be a visionary by his peers and colleagues. He inspires those he mentors with his ability to focus on complicated scientific problems and to deconstruct the issues to the simplest form, providing applicable and practical solutions.

A leader in the field of developing biologics, Lorin Roskos, Ph.D., Senior Director at Abgenix Inc., is motivated by scientific reason and logic.

# AIR KALALI

# A Great Collaborator

#### A TRUE LEADER IN THE AREA OF CNS DRUG DEVELOPMENT.

Amir Kalali, M.D., is responsible for the medical and scientific aspects of CNS trials at Quintiles Transnational Corp. Dr. Kalali wears two hats: he is VP of medical and scientific services at Quintiles Inc. and global scientific head of Quintiles CNS Therapeutics.

Through these positions, as well as his research and clinical experience, he has observed first hand the myriad challenges — including high placebo responses, subjective outcome measures, and outmoded methodologies — that face drug developers focused on CNS therapeutics. Another obstacle that he has identified is the lack of collaboration among the different pharmaceutical companies to tackle these problems. He believes that to go forward successfully as drug developers, the industry needs to collectively address these issues, otherwise there will be fewer CNS drugs developed.

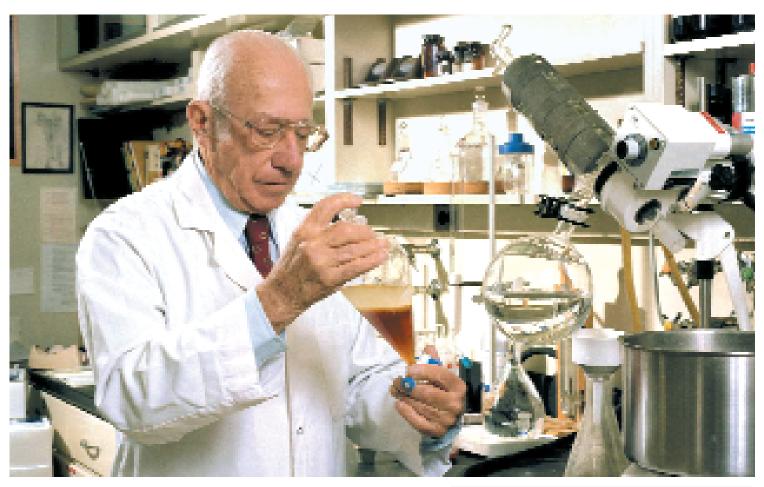
So, rather than shrug his shoulders and succumb to the status quo, Dr. Kalali decided to challenge convention by initiating a collaboration among the various CNS drug-development stakeholders. The result was the International Society for CNS Drug Development (ISCDD), an organization that brings together leaders from industry, academia, and government to fund and improve the methodology of CNS clinical trials.

Always pushing for the highest standards of integrity and ethics in the industry, Dr. Kalali has been a true advocate for changes that will benefit clinical-trial subjects and patients. His efforts have had a tremendous impact, and he has inspired many individuals in the industry to challenge everything they do and to try to improve the way CNS compounds are developed.

As one of the best known figures in CNS drug development, Amir Kalali, M.D., VP of Medical and Scientific Services at Quintiles Inc. and Global Scientific Head of Quintiles CNS Therapeutics, is raising the profile of industry scientists.



# Dr. Leo Sternbach



#### An Inventor's Inventor

A powerful pain reliever and anti-anxiety medication with minimal side effects is just one of the remarkable legacies Dr. Leo H. Sternbach left during his long history with Roche. The inventor of Valium and numerous other medications has been widely acclaimed for his remarkable achievements, including being inducted into the Inventors Hall of Fame in May 2005.

Dr. Sternbach began his pharmaceutical career with Roche in Switzerland, but with the fear of Nazi persecution ever a threat, the company sent its Jewish scientists, Dr. Sternbach included, to the United States.

That was the start of the scientist's long and prolific history with Roche's U.S. headquarters in Nutley, N.J. Even after retiring in 1973, Dr. Sternbach continued to make daily visits to the office, talking to colleagues, consulting, responding to the many letters he received from grateful patients, and writing his memoirs.

The "Doc," as he is affectionately known by his many friends and admirers at Roche, was a true inventor's inventor.

Aside from Valium, compounds to emerge from Dr. Sternbach's lab included Librium, Quarzan, Mogadon, and Klonopin. One of his earliest achievements was the synthesis of biotin, a member of the Vitamin B complex group with important biochemical functions in the metabolism of fat and carbohydrates and in the breakdown of amino acids.

At the same time, Dr. Sternbach has remained a humble man, who thoroughly appreciates interacting with others.

Dr. Sternbach is described by friends and former colleagues as a true inspiration, as a giant of medicinal medicine, and the standard to which all medicinal chemists at Roche would like to aspire. The mark he left on the company is widely appreciated.

"Clearly his legacy has very strongly influenced our culture here in terms of people's desire to have some measure of accomplishment that might be comparable to his. Nobody has come close since Leo," says former colleague and long-time friend Jeff Tilley, Ph.D., senior director of discovery chemistry at Roche.

During his long career with Roche, Dr. Leo H. Sternbach brought relief to millions with his discoveries and huge success to the company he devoted his life to.

# DR. GIULIO VITA

# A Proud Legacy

DR. GIULIO VITA, FORMER PRESIDENT OF SCIENCE AND TECHNOLOGY AT BRISTOL-MYERS, IS REMEMBERED BY HIS COLLEAGUES AND PEERS AS HAVING A SHARP SCIENTIFIC MIND AND A STRAIGHT-FORWARD MANAGEMENT STYLE.

Back in the 1980s, when Bristol-Myers consolidated its three drug units, it did so under the direction of Dr. Vita, a widely respected scientist. It was Dr. Vita's job to mesh the units into one culture in which the pursuit of excellent science was the foremost concern.

According to former colleagues, Dr. Vita's influence was immediate. Under his guidance, researchers were encouraged to gather informally; the thought was that serendipity plays an important role in science, and since one lab's failure can become a triumph for another, it was important to create a culture that fostered the exchange of information and ideas.

Dr. Vita inspired his colleagues with his willingness to take risks and his ability to place research projects, involving a large number of different disease-oriented products, above all else.

For the late President of Science and Technology of Bristol-Myers, Dr. Giulio Vita, the pursuit of excellent science was priority No. 1.

